K041001
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510(k) Summary of Safety and Effectiveness for the Omega™ 2 System

Proprietary Name:	Omega™ 2 System
Common Name:	Compression Screw System
Classification Name and Reference	Single/multiple component metallic bone fixation appliances and accessories 21 CFR §888.3030
Regulatory Class:	Class II
Device Product Code:	87 KTT
For Information contact:	Vivian Kelly, Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5581 Fax: (201) 831-6038
Date Summary Prepared:	April 16, 2004

Description:
The Omega™ 2 System is a compression screw system designed to treat various types of fractures of the proximal and distal femur. The Omega™ 2 System is a modification to the existing Omega™ II, Omega™ Plus and Omega™ Systems. The subject Omega™ 2 System is a line extension to the predicate devices to modify and add new components to the system.

Intended Use:
The Omega™ Plus and 2 Systems are intended for use in the temporary stabilization of fractures of the proximal and distal femur.

Substantial Equivalence:
The design and function of the Omega™ 2 System is substantially equivalent to that of the predicate devices. Both the subject and predicate systems offer different types of plates in varying lengths and angles for use with the other accessories in the system. This system is equivalent to other systems on the market in regards to design, materials, indications and operational principals. Mechanical testing demonstrated comparable mechanical properties to the predicate components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 01 2004

Vivian Kelly
Regulatory Affairs Specialist
Howmedica Osteonics Corporation
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K041001
Trade/Device Name: Omega™ 2 System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: April 16, 2004
Received: April 19, 2004

Dear Ms Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041001

Device Name: Omega™ 2 System

Indications for Use:

The Omega™ Plus and 2 Systems are intended for use in the temporary stabilization of types of fractures of the proximal and distal femur. The subject devices are indicated for fixation of proximal and distal femoral fractures including but not limited to:

- Intracapsular and basal neck fractures including transcervical and subcapital fractures
- Intertrochanteric fractures
- Subtrochanteric fractures
- Supracondylar fractures
- Intracondylar fractures
- Osteotomies for patients with diseases or deformities of the hip
- Hip arthrodesis

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041001